

CLAIMS

What is claimed is:

1. A multi-layer dressing for topical application to a substrate, said dressing comprising:

5 (A) a controlled-release layer formed from a controlled-release composition comprising;

(i) an oil-in-water or water-in-oil emulsion, and

(ii) an active agent incorporated into said emulsion and comprising a protein; and

10 (B) an adhesive layer disposed adjacent said controlled-release layer for adhering said dressing to the substrate; and

(C) an additional layer selected from the group of a backing layer, a cushioning layer, an absorbent layer, a second adhesive layer, and combinations thereof.

2. A dressing as set forth in claim 1 wherein said emulsion has a hydrophilic phase comprising said active agent, water, and a carrier, and a hydrophobic phase comprising a silicone component.

3. A dressing as set forth in claim 2 further comprising a surfactant between said hydrophilic and hydrophobic phases.

4. A dressing as set forth in claim 2 wherein said carrier is in solution with said water.

5. A dressing as set forth in claim 1 wherein said protein is an enzyme.

6. A dressing as set forth in claim 5 wherein said enzyme is selected from the group of oxidoreductases, transferases, isomerases, ligases, hydrolases, cutinases, oxidases, reductases, hemicellulases, esterases, pectinases, lactases, peroxidases, 25 laccases, catalases, antibodies, polypeptides, peptides, hormones, cytokines, growth factors, biological modulators, and combinations thereof.

7. A dressing as set forth in claim 5 wherein said enzyme comprises Protease A, Protease B, or LG12.

8. A dressing as set forth in claim 1 further comprising a dispersing agent for dispersing said active agent.

9. A dressing as set forth in claim 2 wherein said silicone component is selected from the group consisting of a silicone gum, a silicone rubber, a silicone elastomer, a silicone resin, high molecular weight silicones, silicone emulsions, and combinations thereof.

5 10. A dressing as set forth in claim 2 wherein said silicone component comprises a pressure sensitive adhesive.

11. A dressing as set forth in claim 10 wherein said pressure sensitive adhesive comprises the reaction product of;

a hydroxy endblocked polydimethylsiloxane polymer, and

10 a hydroxy functional silicate resin.

12. A dressing as set forth in claim 1 further comprising an excipient.

13. A dressing as set forth in claim 1 wherein said emulsion is said oil-in-water emulsion.

14. A dressing as set forth in claim 13 wherein said oil-in-water emulsion is substantially free of lipophilic solvent and formed by mechanical inversion of a water-in-oil emulsion.

15 15. A dressing as set forth in claim 1 wherein said dressing is a patch.

16. A dressing as set forth in claim 1 wherein said controlled-release layer is adjacent the substrate and said additional layer is disposed adjacent said adhesive layer 20 spaced from said controlled-release layer.

17. A dressing as set forth in claim 1 wherein said controlled-release layer is dry in said dressing such that said controlled-release layer is free of water after said controlled-release layer is formed by said controlled-release composition.

25 18. A dressing as set forth in claim 2 wherein said controlled-release layer is dry in said dressing such that said controlled-release layer is free of water after said controlled-release layer is formed by said controlled-release composition.

19. A multi-layer dressing for topical application to a substrate, said dressing comprising:

(A) a controlled-release layer formed from a controlled-release composition comprising;

5 (i) an oil-in-water emulsion substantially free of lipophilic solvent and formed by mechanical inversion of a water-in-oil emulsion, and

(ii) an active agent incorporated into said emulsion and comprising a protein; and

10 (B) an adhesive layer disposed adjacent said controlled-release layer for adhering said dressing to the substrate.

20. A dressing as set forth in claim 19 wherein said emulsion has a hydrophilic phase comprising said active agent, water, and a carrier, and a hydrophobic phase comprising a silicone component.

21. A dressing as set forth in claim 20 further comprising a surfactant between 15 said hydrophilic and hydrophobic phases.

22. A dressing as set forth in claim 20 wherein said carrier is in solution with said water.

23. A dressing as set forth in claim 19 wherein said protein is an enzyme.

24. A dressing as set forth in claim 23 wherein said enzyme is selected from 20 the group of oxidoreductases, transferases, isomerases, ligases, hydrolases, cutinases, oxidases, reductases, hemicellulases, esterases, pectinases, lactases, peroxidases, laccases, catalases, antibodies, polypeptides, peptides, hormones, cytokines, growth factors, biological modulators, and combinations thereof.

25. A dressing as set forth in claim 23 wherein said enzyme comprises Protease A, Protease B, or LG12.

26. A dressing as set forth in claim 19 further comprising a dispersing agent for dispersing said active agent.

27. A dressing as set forth in claim 20 wherein said silicone component is selected from the group consisting of a silicone gum, a silicone rubber, a silicone elastomer, a silicone resin, high molecular weight silicones, silicone emulsions, and 30 combinations thereof.

28. A dressing as set forth in claim 20 wherein said silicone component comprises a pressure sensitive adhesive.

29. A dressing as set forth in claim 28 wherein said pressure sensitive adhesive comprises the reaction product of;

5 a hydroxy endblocked polydimethylsiloxane polymer, and
 a hydroxy functional silicate resin. }

30. A dressing as set forth in claim 19 further comprising an excipient.

31. A dressing as set forth in claim 19 wherein said dressing is a patch.

32. A dressing as set forth in claim 19 further comprising additional layer
10 selected from the group of a backing layer, a cushioning layer, an absorbent layer, a second adhesive layer, and combinations thereof.

33. A dressing as set forth in claim 19 wherein said controlled-release layer is dry in said dressing such that said controlled-release layer is free of water after said controlled-release layer is formed by said controlled-release composition.

15 34. A dressing as set forth in claim 20 wherein said controlled-release layer is dry in said dressing such that said controlled-release layer is free of water after said controlled-release layer is formed by said controlled-release composition.

35. A controlled-release composition for topical application to a substrate, said composition comprising:

20 an oil-in-water emulsion substantially free of lipophilic solvent and formed by mechanical inversion of a water-in-oil emulsion; and

an active agent incorporated into said emulsion and comprising a protein.

36. A controlled-release composition as set forth in claim 35 wherein said emulsion has a hydrophilic phase comprising said active agent, water, and a carrier, and a
25 hydrophobic phase comprising a silicone component.+

37. A controlled-release composition as set forth in claim 36 further comprising a surfactant between said hydrophilic and hydrophobic phases.

38. A controlled-release composition as set forth in claim 36 wherein said carrier is selected from the group of glycerin, propylene glycol, polyethylene glycol,
30 poloxamer, alcohol, polyhydric alcohol, water, polyvinyl alcohol, polyvinylpyrrolidone, and combinations thereof.

39. A controlled-release composition as set forth in claim 36 wherein said carrier is in solution with said water.

40. A controlled-release composition as set forth in claim 35 wherein said protein is an enzyme.

5 41. A controlled-release composition as set forth in claim 40 wherein said enzyme is selected from the group of natural enzymes, synthetic enzymes, engineered enzymes, and combinations thereof.

10 42. A controlled-release composition as set forth in claim 40 wherein said enzyme is selected from the group of oxidoreductases, transferases, isomerases, ligases, hydrolases, cutinases, oxidases, reductases, hemicellulases, esterases, pectinases, lactases, peroxidases, laccases, catalases, antibodies, polypeptides, peptides, hormones, cytokines, growth factors, biological modulators, and combinations thereof.

15 43. A controlled-release composition as set forth in claim 40 wherein said enzyme comprises Protease A, Protease B, or LG12.

44. A controlled-release composition as set forth in claim 37 further comprising a dispersing agent for dispersing said active agent.

45. A controlled-release composition as set forth in claim 44 wherein said dispersing agent comprises a silicone-based surfactant different from said surfactant.

20 46. A controlled-release composition as set forth in claim 44 wherein said dispersing agent is selected from the group of nonionic surfactants, anionic surfactants, ethers, esters, glycols, and combinations thereof.

47. A controlled-release composition as set forth in claim 44 wherein said active agent is in powder form or crystalline form.

25 48. A controlled-release composition as set forth in claim 47 wherein said dispersing agent encapsulates said active agent.

49. A controlled-release composition as set forth in claim 35 wherein said active agent is in liquid or viscous form.

30 50. A controlled-release composition as set forth in claim 36 wherein said silicone component is selected from the group consisting of a silicone gum, a silicone rubber, a silicone elastomer, a silicone resin, high molecular weight silicones, silicone emulsions, and combinations thereof.

51. A controlled-release composition as set forth in claim 36 wherein said silicone component comprises a pressure sensitive adhesive.

52. A controlled-release composition as set forth in claim 51 wherein said pressure sensitive adhesive comprises the reaction product of;

5 a hydroxy endblocked polydimethylsiloxane polymer, and
a hydroxy functional silicate resin.

53. A controlled-release composition as set forth in claim 52 wherein said hydroxy functional silicate resin is further defined as a trimethylsiloxy and hydroxy endblocked silicate resin.

10 54. A controlled-release composition as set forth in claim 35 further comprising an excipient.

55. A controlled-release composition as set forth in claim 35 wherein a film of said controlled-release composition is formed on the substrate upon topical application of said controlled-release composition to the substrate.

15 56. A method of delivering an active agent comprising a protein to a substrate with a multi-layer dressing, said method comprising the steps of:

providing at least one layer of the dressing;

providing an oil-in-water or water-in-oil emulsion;

20 incorporating the active agent comprising the protein into the emulsion to establish a controlled-release composition;

applying the controlled-release composition to the layer to form a controlled-release layer of the dressing.

25 57. A method as set forth in claim 56 further comprising the step of adhering the dressing to the substrate to deliver the active agent comprising the protein to the substrate.

58. A method as set forth in claim 56 wherein the layer of the dressing is selected from the group of a backing layer, a cushioning layer, an absorbent layer, an adhesive layer, and combinations thereof.

30 59. A method as set forth in claim 56 further comprising the step of encapsulating the active agent in a dispersing agent prior to incorporation of the active agent into the emulsion.

60. A method as set forth in claim 56 further comprising the step of combining the active agent with a dispersing agent to form a dispersion prior to incorporation of the active agent into the emulsion.

5 61. A method as set forth in claim 56 wherein the step of providing the oil-in-water or water-in-oil emulsion further comprises the step of mechanically-inverting a water-in-oil emulsion into the oil-in-water emulsion.

62. A method as set forth in claim 56 wherein the emulsion has a hydrophilic phase comprising the active agent, water, and a carrier, and a hydrophobic phase comprising a silicone component.

10 63. A method as set forth in claim 62 wherein the silicone component is selected from the group consisting of a silicone gum, a silicone rubber, a silicone elastomer, a silicone resin, high molecular weight silicones, silicone emulsions, and combinations thereof.

15 64. A method as set forth in claim 62 wherein the silicone component comprises a pressure sensitive adhesive.

65. A method as set forth in claim 56 further comprising the step of incorporating an excipient into the emulsion.

20 66. A method as set forth in claim 57 wherein the substrate is skin and the step of adhering the dressing to the substrate is further defined as adhering the dressing to the skin to deliver the active agent comprising the protein to the skin.

67. A method as set forth in claim 56 wherein the substrate comprises one of a biological surface, human body tissue, and animal body tissue.

68. A method as set forth in claim 56 wherein the substrate comprises flora.

69. A method as set forth in claim 56 wherein the dressing is a patch.

25 70. A method as set forth in claim 56 wherein the step of applying the controlled-release composition to the layer to form the controlled-release layer is further defined laminating the controlled-release composition onto the layer.

71. A method as set forth in claim 56 further comprising the step of drying the controlled-release composition such that the controlled-release layer is free of water